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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,727	02/25/2004	Joseph L. Mark	65937-0045	2729

10291 7590 12/02/2010

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
12/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,727	MARK, JOSEPH L.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/14/2010 has been entered.

Notice of Amendment

2. In response to the amendment filed on 09/14/2010, amended claim(s) 1 and 14 and cancelled claim(s) 27-30 is/are acknowledged. The current rejection(s) of the claim(s) is/are *withdrawn*. The following new and/or reiterated ground(s) of rejection is/are set forth:

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, 4, 8, 9, 14, 16, 17, 18, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buzzard et al. (US 6,162,187, hereinafter Buzzard) in view of Siegmund (US 4,598,698).

5. For claims 1 and 14, Buzzard discloses biopsy system (5) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) having a fluid connector (50, 60, and 70) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), comprising *inter alia*:

- a vacuum assisted biopsy device (20) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12);
- a first fluid source (the fluid source communicating through 77 and 79) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12);
- a second fluid source (the fluid source communicating through 78 and 80) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12); and
- a fluid connector (50, 60, and 70) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) positioned remotely and proximally from the biopsy device (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), configured to provide the first and second fluid sources in communication with the biopsy device (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), and comprising:
  - a body member (70) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) defined by a first channel (78 and 80) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) and a second channel (77 and 79) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), wherein the second

channel is integrally attached to the first channel such that the second channel intersects with the first channel (the intersection at 76) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12),

- the first channel having a first inlet port (the right inlet of 80 about 37) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) in fluid communication with the first fluid source (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12),
- a first valve (89) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) connected to the first channel (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) and positioned distally of the first inlet port (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) and distally of the first fluid source (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) such that the first valve is in fluid communication with the first inlet port (50, 60, and 70);
- the second channel having a second inlet port (the right inlet of 79 about 35) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) in fluid communication with the second fluid source (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12),
- a second valve (87) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) in fluid communication with the second inlet port (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), wherein the second valve is connected to the second channel (as best seen in Figures 1-4) (column 6 line 13

– column 8 line 12) and positioned distally of the second inlet port (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) and distally of the second fluid source (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) such that the second inlet port is in contact with the second check valve (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), and

- an outlet port (the common port of 76) (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12) in fluid communication with (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), positioned proximally of a tissue receiving opening of the vacuum assisted biopsy device (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), and positioned remotely from the tissue receiving opening of the vacuum assisted biopsy device (as best seen in Figures 1-4) (column 6 line 13 – column 8 line 12), wherein the first valve is selectively opened when a vacuum is created in the fluid connector (column 8 line 13-35).

6. For claims 1 and 14, Buzzard discloses the claimed invention, as set forth and cited above, except for expressly disclosing the first and second valves are first and second check valves. Buzzard discloses that valves (87 and 89) are preferably rotary valves, but explicitly states that other types of valves may be used (column 7 lines 14-18).

7. For claims 1 and 14, Siegmund teaches a biopsy system (the vacuum assisted retrieval instrument/ retrieval mechanism/ biopsy forcep inserted through channel 26 as positively recited in column 1 lines 9-21, column 2 lines 41-46 and 50-52, and column 4

lines 1-4) (as best seen in Figure 2), comprising *inter alia*: a first check valve (28) (as best seen in Figure 6) (column 2 line 53 – column 3 line 37) in fluid communication with a first fluid source and a first inlet port (as best seen in Figures 4-6) (column 2 line 53 – column 3 line 37) and a second check valve (the check valve at 26) (column 2 lines 41-42 and column 3 lines 30-37) in fluid communication with a second fluid source and a second inlet port (as best seen in Figures 4-6) (column 2 line 53 – column 3 line 37).

8. For claims 1 and 14, the claimed invention would have been obvious because the substitution of one known valve for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Buzzard and Siegmund teach the fluid regulation of biopsy systems using valves, it would have been obvious to one skilled in the art at the time of the invention to substitute one valve for the other to achieve the predictable results of increasing the efficacy of fluid management in biopsy devices by using alternate valves in a fluid connector used with the biopsy system to simplify and save time in surgical procedures by providing well known alternate fluid management configurations.

9. For claims 3 and 16, Siegmund teaches the biopsy system and fluid connector, wherein the second check valve includes a resiliently compressible valve member (the valve ball positively recited in column 2 lines 53-59) (as best seen in Figures 5-6) (column 3 lines 30-37).

10. For claims 4 and 17, Siegmund teaches the biopsy system and fluid connector, wherein the second check valve includes a valve seat (the valve spring that biased the

valve ball positively recited in column 2 lines 53-59) (column 3 lines 30-37) adapted to secure the valve member within the second check valve (as best seen in Figures 5-6) (column 3 lines 30-37).

11. For claims 8 and 21, Siegmund teaches the biopsy system and fluid connector, wherein the first check valve exhibits a predetermined cracking pressure (column 3 lines 4-8), and wherein the cracking pressure is dictated by a change of pressure within at least a portion of the biopsy device (column 3 lines 4-8).

12. For claims 9 and 22, Siegmund teaches the biopsy system and fluid connector, wherein the cracking pressure is less than or equal to a pressure resulting from the vacuum created in the fluid connector by the vacuum assisted biopsy device (column 3 lines 4-8).

13. Claims 2 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buzzard et al. (US 6,162,187, hereinafter Buzzard) in view of Siegmund (US 4,598,698) and in further view of Clement (US 5,505,210).

14. For claims 2 and 15, Buzzard in view of Siegmund discloses the claimed invention except for expressly disclosing the first check valve includes a duckbill valve member. Even though Buzzard in view of Siegmund appears silent with respect to a duckbill valve member, Siegmund is expressly concerned with using a ball check valve and explicitly states other check valve structure may be used without departing from the scope of the invention (column 2 lines 53-59). Moreover, Applicant states in the specification that a duckbill-style valve is a well known check valve (paragraph 40)

15. For claims 2 and 15, Clement teaches a biopsy system (10) (as best seen in Figure 14) and a fluid connector (718) (as best seen in Figure 14), comprising *inter alia*: a first check valve (740) (as best seen in Figure 14) (column 12 lines 15-37 and column 14 lines 7-10) including a duckbill valve member (740) (as best seen in Figure 14) (column 12 lines 15-37 and column 14 lines 7-10) for selectively permitting or excluding fluid passage during a medical procedure.

16. Thus for claims 2 and 15, the claimed invention would have been obvious because the substitution of one known check valve for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Buzzard in view of Siegmund and Clement teach using check valves for fluid management during medical procedures, it would have been obvious to one skilled in the art at the time of the invention to substitute one check valve for the other to achieve the predictable results of increasing the efficacy of fluid management via valves in a fluid connector used with a biopsy system to simplify and save time in surgical procedures by providing well known alternate fluid management configurations.

17. Claims 5, 7, 12, 18, 20, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buzzard et al. (US 6,162,187, hereinafter Buzzard) in view of Siegmund (US 4,598,698) and in further view of Miller et al. (US 2002/0082519, hereinafter Miller).

18. For claims 5, 7, 18, and 20, Buzzard in view of Siegmund discloses the claimed invention except for expressly disclosing the first fluid source is a bag of isotonic solution and the second fluid source includes an anesthetic or a haemostatic agent. Even though Sigmund appears silent with respect to what the suitable fluid in the syringe is, Siegmund is expressly concerned with insufflating, irrigating, and vacuuming while removing biopsy samples. The Examiner notes isotonic solutions and anesthetics are well known irrigation fluids used during medical procedures.

19. For claims 5, 7, 18, and 20, Miller teaches a biopsy system and a fluid connector, comprising *inter alia*: a first fluid source is an isotonic solution (saline; paragraphs 141-144) delivered to the system via a hydraulic control system (15) and a second fluid source is an anesthetic (paragraph 90; “anesthetic”) delivered to the system via an irrigation fitting (145).

20. Thus for claims 5, 7, 18, and 20, all of the fluid delivery components are known in Buzzard in view of Siegmund and Miller. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid delivery components as taught by Buzzard in view of Siegmund with the fluid delivery components as taught by Miller to achieve the predictable results of increasing the efficacy of a biopsy system having fluid management therewith to sufficiently perform irrigation during a medical biopsy procedure by configuring it to deliver anesthetics and/or saline.

21. For claims 12 and 25, Buzzard in view of Siegmund discloses the claimed invention except for expressly disclosing the vacuum created in the fluid connector by the vacuum assisted biopsy device is configured to draw a predetermined amount of fluid from the second fluid source through the output port and into the biopsy device when the second fluid source is connected thereto. Even though Buzzard in view of Siegmund appears silent with respect to the use of vacuum to draw predetermined amounts of fluid, Sigmund is expressly concerned with using the fluid connector to aid in delivery of the suitable fluid in the syringe (column 3 lines 10-23).

22. For claims 12 and 25, For claims 5, 7, 18, and 20, Miller teaches a biopsy system and a fluid connector, comprising *inter alia*: a vacuum (paragraphs 141-143, especially 143) created in a fluid connector (192) (paragraphs 141-143, especially 143) by a vacuum assisted biopsy device (300) (paragraphs 141-143, especially 143) is configured to draw a predetermined amount of fluid from a second fluid source (400) (paragraphs 141-143, especially 143) through an output port (the output of pinch valve 402) (paragraphs 141-143, especially 143) and into the biopsy device when the second fluid source is connected thereto (paragraphs 141-143, especially 143).

23. Thus for claims 12 and 25, all of the fluid management components are known in Buzzard in view of Siegmund and Miller. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid management components as taught by Buzzard in view of Siegmund with the fluid management components as taught by Miller to achieve the predictable results of increasing the

efficacy of a biopsy system having fluid management therewith to sufficiently perform fluidic irrigation during a medical biopsy procedure by configuring it to automatically deliver saline via a valved operation.

24. Claims 6, 10, 19, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buzzard et al. (US 6,162,187, hereinafter Buzzard) in view of Siegmund (US 4,598,698) and in further view of Moore (US 2,866,457).

25. For claims 6 and 19, Buzzard in view of Siegmund discloses the claimed invention except for expressly disclosing the second fluid source includes a needleless syringe. However Siegmund is expressly concerned with configuring another fluid source including a needless syringe (syringe 33) (as best seen in Figures 2 and 4) (column 2 line 53 – column 3 line 37), just not the second fluid source as cited.

26. For claims 6 and 19, Moore teaches a medical device having fluidic administration management comprising check valves (column 1 line 56 – column 2 line 44) including a second fluid source including a needless syringe (26) (as best seen in Figure 1).

27. Thus for claims 6 and 19, all of the fluid management components are known in Buzzard in view of Siegmund and Moore. The only difference is the combination of the fluid management component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid management components as taught by Buzzard in view of Siegmund with the fluid

management components as taught by Moore to achieve the predictable results of increasing the efficacy of a biopsy system having fluid management therewith to sufficiently perform fluidic vacuum, irrigation and/or administration during a medical procedure by configuring it with suitable fluid sources for a variety of functions.

28. For claims 10 and 23, Buzzard in view of Siegmund discloses the claimed invention except for expressly disclosing the cracking pressure is greater than a pressure resulting from the vacuum created in the fluid connector by the vacuum assisted biopsy device when the second check valve is open. Even though Siegmund appears silent with respect to the cracking pressure of the first check valve being greater when the second check valve is open, Siegmund is expressly concerned with configuring the cracking pressure of the check valves to appropriately effect fluid management (column 2 lin3 53 - column 3 line 37).

29. For claims 10 and 23, Moore teaches a medical device having fluidic administration management comprising check valves (column 1 line 56 – column 2 line 44) therein and that it is desirable to keep the two fluid sources isolated and that fluid can not pass the check valves in a wrong direction (column 2, lines 15-18). Thus, the cracking pressure is greater than a vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source.

30. Thus for claims 10 and 23, all of the fluid management components are known in Buzzard in view of Siegmund and Moore. The only difference is the combination of the

fluid management component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid management components as taught by Buzzard in view of Siegmund with the fluid management components as taught by Moore to achieve the predictable results of increasing the efficacy of a biopsy system having fluid management therewith to sufficiently perform fluidic irrigation and/or administration during a medical procedure by configuring it to automatically prevent fluid flow in a wrong direction via suitable check valve(s).

31. Claims 11, 13, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buzzard et al. (US 6,162,187, hereinafter Buzzard) in view of Siegmund (US 4,598,698) and in further view of Turturro et al. (US 6,331,165 B1, hereinafter Turturro).

32. For claims 11, 13, 24, and 26, Buzzard in view of Siegmund discloses the claimed invention except for expressly disclosing the second check valve includes a female luer fitting, the second fluid source includes a male luer fitting adapted to mate with the female luer fitting, and the first and second check valves include a female luer fitting. Siegmund appears silent with respect to the coupling and/or fitting of the check valves to the fluid sources; however, it is well known in the art to provide couplings and fittings between valves and fluid sources in fluidic communication. Moreover, male and female luer fittings are well known in the art of fluidic connections between valves and fluid sources and are routinely used.

33. For claims 11, 13, 24, and 26, Turturro teaches a biopsy system and a fluid connector, comprising *inter alia*: providing male and female luer fittings between irrigation fluid sources and valves (column 18 line 16 – column 19 line 15) (as best seen in Figure 28) for the purpose of providing quick and easy connection and disconnection.

34. Thus for claims 11, 13, 24, and 26, all of the fluid management components are known in Buzzard in view of Siegmund and Turturro. The only difference is the combination of the fluid management component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid management components as taught by Buzzard in view of Siegmund with the fluid management components as taught by Turturro to achieve the predictable results of increasing the efficacy of a biopsy system having fluid management therewith to sufficiently perform fluidic irrigation and/or administration during a medical procedure by configuring it with luer type connection fittings/couplings to establish and ensure fluid is contained in the system and to provide a means for quickly and easily connecting and disconnecting the fluidic components.

Response to Arguments

35. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736